STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Healthcare Quality And Safety Branch

December 21, 2018

Dawn Rudolph, CEO
St Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

Dear Ms. Rudolph:

Unannounced visits were made to St. Vincent's Medical Center on December 6 and 7, 2018 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting an investigation.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which was/were noted during the course of the visits.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by January 4, 2019.

The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;

(2) the date each such corrective measure or change by the institution is effective;

(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and

(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by January 4, 2019 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

An office conference has been scheduled for January 10, 2019 at 10:00am in the Facility Licensing and Investigations

DATES OF VISIT: December 6 and 7, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Heidi Caron, MSN, RN, BC, CLNC
Supervising Nurse Consultant
Facility Licensing and Investigations Section

HAC:lst

CT #24381

DATES OF VISIT: December 6 and 7, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (1) and/or (3) and/or (e) Nursing Service (1) and/or (i) General (C).

1. Based on medical record review, review of facility competencies, review of facility staffing and interviews, the facility failed to ensure that Registered Nurses (RN) who worked on specialty units were adequately trained. The finding includes:
   a. Patient#1 was admitted to the hospital on 3/16/18. Patient #1's history included hypertension and MI (myocardial infarction) times two and was admitted to the Observation (7E) unit on 3/16/18 at 12:32 AM for monitoring. Review of physician orders by APRN (Advanced Practice Registered Nurse) #1 dated 3/16/18 at 12:42 AM directed to monitor the patient with remote telemetry that was verified/signed by RN #3 at 12:45 AM. Review of the Observation unit RN competencies identified that a monitoring class and ACLS (advanced cardiac life support) were required unit training.

      Interview with RN #3 on 12/7/18 at 8:36 AM noted that she floated to the observation unit at 11:00 PM on 3/15/18, had never worked on the observation unit prior to this and had basic but not advanced cardiac life support training. Interview with Director #1 on 12/6/18 at 11:52 AM noted that ACLS certification was required on the observation unit as well as a cardiac dysrhythmia course.

      In addition, review of the staffing for the float pool dated 3/15/18-3/16/18 identified that RN #4 worked on the cardiac (6N) unit during this timeframe. The 6S/N unit RN competency identified that a monitoring class and ACLS (advanced cardiac life support) were required unit training.

      Interview with Director #1 on 12/6/18 at 1:30 PM noted that ACLS training for the float pool staff was required and they became aware that RN #4 was not ACLS trained on 3/16/18 and is in the process of being trained.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (1) and/or (3) and/or (e) Nursing Service (1) and/or (i) General (6).

2. Based on medical record reviews, review of facility documentation, review of facility practice and policies for three of ten patients (P #1, #5 and #6), the facility failed to ensure that cardiac monitoring was initiated timely. The finding includes:
   a. Patient #1's was admitted to the Emergency Department on 3/16/18 with complaints of Chest Pain. Patient #1's history included hypertension, MI (myocardial infarction) times two, pulmonary embolism and a IVC (inferior vena cava) filter. Cardiac testing was negative in the ED (EKG cardiac enzymes), Patient #1 was bradycardic (low pulse in 50's) and the physician assessment/plan was to place on remote telemetry, cycle cardiac enzymes, observation status and full code. Review of facility documentation (time line) indicated that the patient arrived on the observation (7E) unit on 3/16/18 at

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12:32 AM. Review of an order by APRN (Advanced Practice Registered Nurse) #1 dated 3/16/18 at 12:42 AM directed remote telemetry and was verified/signed by RN #3 at 12:45 AM. Review of the medication record noted that Patient #1 received an antihypertensive medication, hydralazine, intravenously and tums for epigastric pain/discomfort at 1:08 AM as ordered. Review of facility documentation indicated that RN #3 assisted Patient #1 to the bathroom and Patient #1 vomited a small amount of digested material. Patient #1's BP (blood pressure) documented on 3/16/18 at 1:59 AM identified that the patient's blood pressure was slightly lower, 180/89 than the previous BP of 204/91 documented at 1:13 AM and 1:22 AM. Further review identified that the initiation of remote telemetry and/or cardiac monitoring was not documented in the patient's record following order verification on 3/16/18 from 12:45 AM to 2:35 AM (1 hour 50 minutes). The facility "time line" noted that RN #3 found Patient #1 unresponsive at 2:33 AM. Review of the cardiac flow sheet dated 3/16/18 identified a time of

2:35 AM for initiation of cardiopulmonary resuscitation for asystole, the patient was intubated and was resuscitated for 16 minutes unsuccessfully. Review of the progress notes by the Intensivist who ran the code (MD #1) and dated 3/16/18 indicated that the exact "downtime" of the patient was unknown as the patient was not on a monitored bed and "downtime" was not greater than 10-15 minutes. Review of the death certificate dated 3/16/18 identified cardiac arrest as the immediate cause of death. A call for interview with RN #3 was placed on 12/6/18 and returned on 12/7/18. Interview with RN #3 on 12/7/18 at 8:36 AM noted that she floated to the observation unit at 11:00 PM on 3/15/18 and had never worked on the observation unit prior to this. RN #3 further indicated that she saw the remote telemetry order, helped settle the patient and gave the patient medications. RN #3 noted that she was documenting outside of Patient #1's room, no longer heard the patient belching, went into the room, found the patient unresponsive and she initiated CPR (cardiopulmonary resuscitation). Further interview with RN #3 on 12/7/18 at 8:36 AM identified that she was aware of the process for obtaining remote telemetry monitors and recalled thinking that she had yet to get the telemetry monitor.

b. Patient #5 was admitted to the 9N unit at 8:45 PM on 11/16/18 with diagnoses of weakness, fever and abnormal laboratory testing. Review of the physician order for remote telemetry on 11/16/18 identified that the the order was documented and verified by the RN at 8:56 PM. Review of Patient #5's clinical record and interview with Director #1 on 12/6/18 at 10:33 AM identified that the first monitored reading/initiation of the cardiac monitor was documented at 10:36 PM on 11/16/18 (1 hour 37 minutes after RN verification).

c. Patient #6 was admitted to 7N unit on 12/3/18 at 5:31 PM with a diagnosis of upper gastrointestinal bleed. Review of the physician order for remote telemetry dated 12/3/18 at 9:59 PM was verified by the RN at 10:02 PM. Review of patient's clinical record and interview with Director #1 on 12/6/18 at 10:40 AM identified that the first monitored reading/initiation of the cardiac monitor was documented at 1:00 AM on 12/4/18 (2 hours 58 minutes after RN verification).

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Interview with Director #1 on 12/6/18 at 10:49 AM noted that the expected timeframe for remote telemetry monitor placement was within one hour after the RN reads the order. The facility remote telemetry policy lacked direction for obtaining the monitor and/or timeframe for placement. The facility staff nurse job description identified a responsibility to note and carry out physician orders.

Subsequent to the event, RN #3 received education regarding remote telemetry monitoring and timely placement. In addition, the hospital attempts to conduct audits regarding the timeliness of remote monitor placement were unsuccessful due to a changes in the computerized system. The facility submitted an immediate action plan to include remote telemetry policy revisions, staff education and audits regarding the timeliness of remote telemetry initiation.